ONC 21st Century Cures Act Notice of Proposed Rulemaking Overview and Q & A

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- ONC must protect the rulemaking process and comply with the Administrative Procedure Act. During the rulemaking process, ONC can only present the information that is in the NPRM as it is contained in the NPRM. ONC cannot interpret that information, nor clarify or provide any further guidance.

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- Please submit comments through the formal process outlined in the Federal Register.

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Agenda

- Purpose of the Rule

- Deregulatory Actions for Previous Rulemakings

- Updates to the 2015 Edition Certification Criteria

- Conditions and Maintenance of Certification

- Enforcement of the Conditions and Maintenance of Certification Requirements

- Modifications to the ONC Health IT Certification Program

- Information Blocking

- Health IT for Pediatric Care and Practice Settings

- Additional Requests for Information

- Timeline

- Q & A

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Implementation of the 21st Century Cures Act

KEY PROVISIONS IN TITLE IV OF THE CURES ACT	ONC'S WORK IN SUPPORT OF THE CURES ACT
Sec. 4001 Pediatrics	• ONC engaged with stakeholders in the public and private sector. • ONC developed ten recommendations for the voluntary certification of health IT for pediatric care in response to the requirement set forth by Congress in Section 4001 of the Cures Act. • ONC proposes to adopt new and revised certification criteria to support the voluntary certification of health IT for use by pediatric health providers to support the health care of children. • ONC is also focused on non-regulatory initiatives that are nimble and responsive to stakeholders, including development of informational resources to support setting-specific implementation that aligns with the ONC Health IT Certification Program.
Sec. 4002 Conditions of Certification	• ONC proposes an approach whereby the Conditions and Maintenance of Certification express initial and ongoing requirements for health IT developers and their certified Health IT Modules. • The Conditions of Certification with accompanying Maintenance of Certification requirements, consistent with the Cures Act, would focus on: (a) information blocking; (b) assurances; (c) communications; (d) application programming interfaces (APIs); (e) real world testing of certified health IT; and (f) attestations. • ONC proposes an enforcement approach to encourage consistent compliance with the requirements. The proposed rule outlines a corrective action process for ONC to review and take action for potential or known instances where a Condition or Maintenance of Certification requirement is not being met by a health IT developer under the ONC Health IT Certification Program.
Sec. 4003 Interoperability Definition	• ONC proposes that interoperability means, with respect to health IT, such health IT that: (1) enables the secure exchange of electronic health information (EHI) with, and use of EHI from, other health IT without special effort on the part of the user; (2) allows for complete access, exchange, and use of all electronically accessible health information for authorized use under applicable state or federal law; and (3) does not constitute information blocking • The proposed definition is consistent with the Cures Act interoperability definition.

Implementation of the 21st Century Cures Act

KEY PROVISIONS IN TITLE IV OF THE CURES ACT	ONC'S WORK IN SUPPORT OF THE CURES ACT
Sec. 4004 Information Blocking	• ONC proposes seven categories of practices that would be considered reasonable and necessary that, provided certain conditions are met, would not constitute information blocking. These categories were developed based on feedback from stakeholders and consultation with appropriate federal agencies. • If the actions of a regulated actor (health care provider, health IT developer, or health information exchange or network) satisfy an exception, the actions would not be treated as information blocking and the actor would not be, as applicable, subject to civil penalties or other disincentives under the law.
Sec. 4005 Exchange with Registries	• ONC's proposed rule includes a Request for Information (RFI) on how a standards-based API might support improved information exchange between a health care provider and a registry in support of public health reporting, quality reporting, and care quality improvement. • Public input on this RFI may be considered for future HHS rulemaking to support the bidirectional exchange of clinical data between health care providers and registries for a wide range of use cases.
Sec. 4006 Patient Access	• ONC proposes to promote policies that would ensure a patient's EHI is accessible to that patient and the patient's designees, in a manner that facilitates communication with the patient's health care providers and other individuals, including researchers, consistent with such patient's consent through the following proposals: United States Core Data for Interoperability (USCDI) standard; "EHI export" criterion; "standardized API for patient and population services" criterion, "data segmentation for privacy (DS4P)" criteria, "consent management for APIs" criterion; API Condition of Certification; and information blocking requirements, which include providing patients access to their EHI at no cost to them. • Patient access to their EHI would be improved through the adoption of the following proposed 2015 Edition standard and certification criteria: USCDI standard; standardized APIs for patient and population services; and EHI export.

Implementation of Executive Orders

EXECUTIVE ORDERS	ONC'S WORK IN SUPPORT OF EXECUTIVE ORDERS
Executive Order 13813 Promoting Healthcare Choice and Competition Across the United States	• ONC's proposed rule would contribute to fulfilling Executive Order 13813 by furthering patient (and health care provider) access to EHI and supporting competition in health care markets through new tools to access EHI and policies to address the hoarding of EHI. • ONC's proposed rule calls on the health care industry to adopt standardized APIs, which would allow individuals to securely and easily access structured EHI using new and innovative applications for smartphones and other mobile devices. • The proposed rule would establish information blocking provisions, focusing on improving patient and health care provider access, exchange, and use of EHI.
Executive Orders 13771 & 13777 Reducing Regulation and Controlling Regulatory Costs, and Enforcing the Regulatory Reform Agenda	• ONC reviewed and evaluated existing regulations to identify ways to reduce burden and implement deregulatory actions. • ONC proposes potential deregulatory actions that will reduce burden for health IT developers, providers, and other stakeholders. These six deregulatory actions are: (1) removal of a threshold requirement related to randomized surveillance; (2) removal of the 2014 Edition from the Code of Federal Regulations (CFR); (3) removal of the ONC-Approved Accreditor (ONC-AA) from the Certification Program; (4) removal of certain 2015 Edition certification criteria; (5) removal of certain Certification Program requirements; and (6) recognition of relevant Food and Drug Administration (FDA) certification processes with a request for information on the potential development of new processes for the ONC Health IT Certification Program.

Purpose

Increase Innovation and Competition
by giving patients and their health care providers safe and secure access to health information and to new tools, allowing for more choice in care and treatment.

Reduce Burden and Advance Interoperability
through the use of United States Core Data for Interoperability (USCDI) standard, new API requirements, and EHI export capabilities for the purposes of switching health IT or to provide patients their electronic health information.

Promote Patient Access
through a provision requiring that patients can electronically access *all* of their electronic health information (structured and/or unstructured) at no cost.

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https://www.healthit.gov/NPRM

Deregulatory Actions for Previous Rulemakings

Deregulatory Actions for Previous Rulemakings

Since the inception of the ONC Health IT Certification Program, ONC has aimed to implement and administer the ONC Health IT Certification Program in the least burdensome manner that supports our policy goals. Throughout the years, we have worked to improve the ONC Health IT Certification Program with a focus on ways to:

REDUCE BURDEN

OFFER FLEXIBILITY TO BOTH DEVELOPERS AND PROVIDERS

SUPPORT INNOVATION

EXECUTIVE ORDERS

In 2017, the President issued **Executive Orders 13771** and **13777** that require agencies to identify deregulatory actions and establish a process by which agencies review and evaluate existing regulations and make recommendations for repeal or simplification.

UPDATES TO THE ONC HEALTH IT CERTIFICATION PROGRAM

ONC has reviewed and evaluated existing ONC Health IT Certification Program regulations to identify ways to further reduce administrative burden, to implement deregulatory actions through guidance, and to propose potential new deregulatory actions in the proposed rule that will reduce burden for health IT developers, health care providers, and other stakeholders. **The proposed rule can be accomplished through six deregulatory activities:**

1. Removal of Randomized Surveillance Requirements
2. Removal of the 2014 Edition from the Code of Federal Regulations
3. Removal of the ONC-Approved Accreditor (ONC-AA) from the ONC Health IT Certification Program
4. Removal of Certain 2015 Edition Certification Criteria and Standards
5. Removal of Certain Program Requirements
6. Recognition of Food and Drug Administration (FDA) Processes

Updates to the 2015 Edition Certification Criteria

Updates to the 2015 Edition Certification Criteria

This rule proposes to update the 2015 Edition by not only proposing criteria for removal, but by proposing to revise and add new certification criteria that would establish the capabilities and related standards and implementation specifications for the certification of health IT.

https://www.healthit.gov/sites/default/files/understanding-certified-health-it-2.pdf *

*Note: this is a link to the current certification criteria but it will need to be updated after the Cures Act final rule is released.

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Proposed Changes to the 2015 Edition Certification Criteria

Removed Criteria

2015 Base EHR Definition Criteria
- x Problem list (§ 170.315(a)(6))
- x Medication list (§ 170.315(a)(7))
- x Medication allergy list (§ 170.315(a)(8))
- x Smoking status (§ 170.315(a)(11))

Other Criteria
- x Drug formulary and preferred drug list checks (§ 170.315(a)(10)
- x Patient-specific education resource (§ 170.315(a)(13))
- x Common Clinical Data Set summary record – create (§ 170.315(b)(4))
- x Common Clinical Data Set summary record – receive (§ 170.315(b)(5))
- x Secure messaging (§ 170.315(e)(2))

Updated Criteria

Remove	Update with
x Electronic prescribing (§ 170.315(b)(3))	✓ Electronic prescribing (§ 170.315(b)(11))
x Data export (§ 170.315(b)(6))	✓ Electronic health information (EHI) export (§ 170.315(b)(10))
x Data segmentation for privacy – send (§ 170.315(b)(7))	✓ Data segmentation for privacy – send (§ 170.315(b)(12))
x Data segmentation for privacy – receive (§ 170.315(b)(8))	✓ Data segmentation for privacy – receive (§ 170.315(b)(13))
x Application access – data category request (§ 170.315(g)(8))	✓ Standardized API for patient and population services (§ 170.315(g)(10))

Revised Criteria

- ✓ Clinical Quality Measures (CQMs) – report criterion (§ 170.315(c)(3))
- ✓ Common Clinical Data Set/United States Core Data for Interoperability criteria (170.315(b)(1), (e)(1), (f)(5), (g)(6), and (g)(9))
- ✓ C-CDA Companion Guide criteria (The above listed criteria and § 170.315(b)(2) and (b)(9))
- ✓ Certification criteria that reference minimum standards code sets (§ 170.315(a)(12), (f)(1), and (f)(2)

New Criteria

- + Encrypt authentication credentials (§ 170.315(d)(12))
- + Multi-factor authentication (MFA) (§ 170.315(d)(13))
- + Consent management for application programming interfaces (§ 170.315(g)(11))

Conditions and Maintenance of Certification

Conditions and Maintenance of Certification

The 21st Century Cures Act (Section 4002) requires the Secretary of HHS to establish Conditions and Maintenance of Certification requirements for the ONC Health IT Certification Program

ONC proposes an approach whereby the Conditions and Maintenance of Certification express initial requirements and ongoing requirements for health IT developers and their certified Health IT Module(s). Any noncompliance with the proposed Conditions and Maintenance of Certification requirements would be subject to ONC direct review, corrective action, and enforcement procedures under the ONC Health IT Certification Program.

There are seven Conditions of Certification with accompanying Maintenance of Certification Requirements. They are:

1. **Information Blocking**

2. **Assurances**

3. **Communications**

4. **Application Programming Interfaces (APIs)**

5. **Real World Testing**

6. **Attestations**

7. *(Future) Electronic Health Record (EHR) Reporting Criteria Submission*

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Enforcement of the Conditions and Maintenance of Certification Requirements

Enforcement Approach

ONC DIRECT REVIEW OF THE CONDITIONS AND MAINTENANCE OF CERTIFICATION

- ONC would be the sole party responsible for enforcing compliance. ONC may, however, coordinate its review with the HHS Office of Inspector General (OIG) or defer to the OIG to lead review of a claim of information blocking.

- ONC will utilize the processes established for ONC direct review of certified health IT in the Enhanced Oversight and Accountability (EOA) final rule for enforcement. Using the established processes delivers multiple benefits:

  - EOA processes address non-conformities with Program requirements. Any noncompliance with the Conditions and Maintenance of Certification would constitute a Program non-conformity

  - Health IT developers are familiar with the ONC direct review provisions

  - The processes established for working with health IT developers is thorough and transparent, with clear corrective action procedures and remedies for Program non-conformities

  - Direct review provides equitable opportunities for health IT developers to respond to ONC actions and appeal certain determinations

Enforcement Approach

STEP 1 Initiating Review and Health IT Developer Notice

STEP 2 Records Access

STEP 3 Corrective Action Plan

STEP 4 Certification Ban and/or Termination

STEP 5 Appeal

STEP 6 Public Listing of Certification Ban and/or Terminations

Modifications to the ONC Health IT Certification Program

Modifications to the ONC Health IT Certification Program – Updates to the Principles of Proper Conduct

ONC-ACBs MUST NOW:

1. Accept test results from any ONC-ATL in good standing.

2. Review and confirm health IT developer submission of real world testing plans and results and make plans and results publicly available.

3. Collect health IT developers' quarterly attestations and note in Certified Health IT Product List (CHPL) when Health IT Modules are updated under the Standards Version Advancement Process (VAP) flexibility.

4. Ensure that health IT developers seeking to take advantage of the Standards VAP flexibility comply with the applicable requirements, retain records of the timing and content of developers' § 170.405(b)(5) notices, and timely post each notice's content publicly on the CHPL.

5. Review and submit health IT developer Conditions and Maintenance of Certification attestations to ONC for public availability.

6. Report to ONC any information that could lead ONC to perform direct review, including potential noncompliance with a Condition of Certification.

NEW FLEXIBILITIES FOR ONC-ACBs:

1. The role of the ONC-AA would be eliminated, permitting ONC-ACBs to select the ISO/IEC 17065 accreditation body of their choice.

2. Certain randomized surveillance requirements would be eliminated.

3. ONC-ACBs would be able to certify Health IT Modules that they have evaluated for conformance with certification criteria without first passing through an ONC-ATL as long as conformity methods were approved by the National Coordinator.

NO LONGER REQUIRED:

1. Certain disclosure requirements regarding certified health IT limitations.

2. Transparency attestations by health IT developer regarding the sharing of information in its mandatory disclosures.

Information Blocking

Information Blocking

⭐ Section 4004 of the Cures Act authorizes the Secretary to identify reasonable and necessary activities that do not constitute information blocking.

⭐ In consultation with stakeholders, we have identified seven categories of practices that would be reasonable and necessary, provided certain conditions are met.

"Actors" regulated by the information blocking provision:

- Health Care Providers
- Health IT Developers of Certified Health IT
- Health Information Exchanges
- Health Information Networks

⭐ The seven categories of reasonable and necessary practices, and their corresponding conditions, are defined through the exceptions proposed at 45 CFR 171.201–207.

⭐ If the actions of a regulated actor (health care provider, health IT developer, or health information exchange or network) satisfy one or more exception, the actions would not be treated as information blocking and the actor would not be subject to civil penalties and other disincentives under the law.

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What Makes an Individual or Entity an Information Blocker?

- **Information blocking definition**

  A practice by a health care provider, health IT developer, health information exchange, or health information network that, except as required by law or specified by the Secretary as a reasonable and necessary activity, is likely to interfere with, prevent, or materially discourage access, exchange, or use of electronic health information.

- **Elements of information blocking**

  ❑ Actor regulated by the information blocking provision

  ❑ Involves electronic health information (EHI)

  ❑ Practice is likely to interfere with, prevent, or materially discourage access, exchange, or use of EHI

  ❑ Requisite knowledge by the actor

  ❑ Not required by law

  ❑ Not covered by an exception

Electronic Health Information

- We propose to define EHI to mean electronic protected health information (as defined in HIPAA), and any other information that:

  » is transmitted by or maintained in electronic media (as defined in 45 CFR 160.103);

  » identifies the individual, or with respect to which there is a reasonable basis to believe the information can be used to identify the individual;

  » relates to the past, present, or future health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual.

- Not limited to information that is created or received by a health care provider.

- Does not include health information that is de-identified consistent with the requirements of 45 CFR 164.514(b).

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Price Information – Request for Comments and Information

- The fragmented and complex nature of pricing within the health care system has decreased the efficiency of the health care system and has had negative impacts on patients, health care providers, health systems, plans, plan sponsors and other key health care stakeholders.

- ONC has a unique role in setting the stage for such future actions by establishing the framework to prevent the blocking of price information.

  » We seek comment on the parameters and implications of including price information within the scope of EHI for purposes of information blocking.

- Consistent with its statutory authority, the Department is considering subsequent rulemaking to expand access to price information for the public, prospective patients, plan sponsors, and health care providers.

  » The overall Department seeks comment on the technical, operational, legal, cultural, environmental and other challenges to creating price transparency within health care.

Information Blocking Exceptions

- **§ 171.201 Exception** | Preventing Harm

  » An actor may engage in practices that are reasonable and necessary to prevent physical harm to a patient or another person.

  » The actor must have a reasonable belief that the practice will directly and substantially reduce the likelihood of physical harm to a patient or another person.

  » The practice must implement an organizational policy that meets certain requirements or must be based on an individualized assessment of the risk in each case.

  > This proposed exception acknowledges that the public interest in protecting patients and other persons against unreasonable risks of harm can justify practices that are likely to interfere with access, exchange, or use of electronic health information (EHI).

- **§ 171.202 Exception** | Promoting the Privacy of Electronic Health Information

  » An actor may engage in practices that protect the privacy of EHI.

  » An actor must satisfy at least one of four discrete sub-exceptions that address scenarios that recognize existing privacy laws and privacy-protective practices: (1) practices that satisfy preconditions prescribed by privacy laws; (2) certain practices not regulated by HIPAA but which implement documented and transparent privacy policies; (3) denial of access practices that are specifically permitted under HIPAA; (4) practices that give effect to an individual's privacy preferences.

  » The information blocking provision will not require that actors provide access, exchange, or use of EHI in a manner that is not permitted under the HIPAA Privacy Rule.

  » General conditions apply to ensure that practices are tailored to the specific privacy risk or interest being addressed and implemented in a consistent and non-discriminatory manner.

  > This proposed exception would advance the goal of preventing information blocking for improper or self-interested purposes while maintaining and upholding the privacy rights that patients now have.

Information Blocking Exceptions

- **§ 171.203 Exception** | Promoting the Security of Electronic Health Information

  » An actor may implement measures
    to promote the security of EHI.
  » The practice must be directly related to safeguarding
    the confidentiality, integrity, and availability of EHI.
  » The practice must be tailored to specific security risks and
    must be implemented in a consistent and non-discriminatory manner.
  » The practice must implement an organizational security policy that meets certain requirements or must be based on
    an individualized determination regarding the risk and response in each case.

  > This proposed exception would protect actors who mitigate security risks and implement appropriate safeguards to secure the EHI they control.

- **§ 171.204 Exception** | Recovering Costs Reasonably Incurred

  » An actor may recover costs that it reasonably incurs,
    in providing access, exchange, or use of EHI.
  » Fees must be:
    (1) charged on the basis of objective and verifiable
    criteria uniformly applied to all similarly situated
    persons and requests; (2) related to the costs of providing
    access, exchange, or use; and (3) reasonably allocated
    among all customers that use the product/service.
  » Fees must not be based on anti-competitive or other impermissible criteria.
  » Certain costs would be specifically excluded from coverage under this exception, such as costs that are speculative or
    subjective or costs associated with electronic access by an individual to their EHI.

  > This proposed exception acknowledges that actors should be able to recover costs that they reasonably incur to develop technologies and provide services that enhance interoperability and promote innovation, competition, and consumer welfare.

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Information Blocking Exceptions

- **§ 171.205 Exception** | Responding to Requests that are Infeasible

  » An actor may decline to provide access, exchange, or use of EHI in a manner that is infeasible.

  » Complying with the request must impose a substantial burden on the actor that is unreasonable under the circumstances (taking into account the cost to the actor, actor's resources, etc.).

  » The actor must timely respond to infeasible requests and work with requestors to provide a reasonable alternative means of accessing the EHI.

  > This proposed exception acknowledges that there may be legitimate practical challenges beyond an actor's control that may limit its ability to comply with requests for access, exchange, or use of EHI.

- **§ 171.206 Exception** | Licensing of Interoperability Elements on Reasonable and Non-discriminatory Terms

  » An actor that controls technologies or other interoperability elements that are necessary to enable access to EHI will not be information blocking so long as it licenses such elements on reasonable and non-discriminatory terms.

  > This proposed exception would allow actors to protect the value of their innovations and earn returns on the investments they have made to develop, maintain, and update those innovations.

  » The license can impose a reasonable royalty but must include appropriate rights so that the licensee can develop, market, and/or enable the use of interoperable products and services.

  » The terms of the license must be based on objective and verifiable criteria that are uniformly applied and must not be based on impermissible criteria, such as whether the requestor is a potential competitor.

Information Blocking Exceptions

- **§ 171.207 Exception** | Maintaining and Improving Health IT Performance

  » An actor may make health IT under its control temporarily unavailable in order to perform maintenance or improvements to the health IT.

  » An actor must ensure that the health IT is unavailable for no longer than necessary to achieve the maintenance or improvements.

  » The practice must be implemented in a consistent and non-discriminatory manner.

  » In circumstances when health IT is supplied to an individual or entity, the individual or entity (e.g., customer) must agree to the unavailability of health IT.

  The proposed exception recognizes that it may be reasonable and necessary for actors to make health IT, and in turn EHI, temporarily unavailable for the benefit of the overall performance of health IT.

Complaint Process and Requests for Information

- **Complaint Process**
  - » Section 3022(d)(3)(A) of the PHSA directs the National Coordinator to implement a standardized process for the public to submit reports on claims of health information blocking.
  - » We intend to implement and evolve this complaint process by building on existing mechanisms, including the complaint process currently available at https://www.healthit.gov/healthit-feedback.
  - » We request comment on this approach and any alternative approaches that would best effectuate this aspect of the Cures Act.

- **Additional Exceptions**
  - » We are considering whether we should propose, in a future rulemaking, a narrow exception to the information blocking provision for practices that are necessary to comply with the requirements of the Common Agreement.
  - » We welcome comment on any potential new exceptions we should consider for future rulemaking.

- **Disincentives for Health Care Providers**
  - » We request information on disincentives or if modifying disincentives already available under existing HHS programs and regulations would provide for more effective deterrents.

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Health IT for Pediatric Care and Practice Settings

Health IT for Pediatric Care and Practice Settings

In response to the requirements set forth in section 4001 of the Cures Act, ONC has:

1 Developed ten recommendations for the voluntary certification of health IT for pediatric care that does NOT include a separate certification program for pediatric care and practice settings.

2 Identified current and proposed new 2015 Edition certification criteria that support pediatric care and practice settings.

3 Focused on non-regulatory initiatives that are nimble and responsive to stakeholders, including development of informational resources to support setting-specific implementation that aligns with the ONC Health IT Certification Program.

Health IT for Pediatric Care and Practice Settings

ONC DEVELOPED RECOMMENDATIONS BASED ON STAKEHOLDER-IDENTIFIED CLINICAL PRIORITIES AND THE CHILDREN'S EHR FORMAT

Pediatric stakeholders identified clinical priorities and evaluated them with ONC.

Access Children's EHR Format Here

ONC RECOMMENDATIONS FOR PEDIATRIC HEALTH IT VOLUNTARY CERTIFICATION CRITERIA

1. Use biometric-specific norms for growth curves and support growth charts for children
2. Compute weight-based drug dosage
3. Ability to document all guardians and caregivers
4. Segmented access to information
5. Synchronize immunization histories with registries
6. Age- and weight-specific single dose range checking
7. Transferrable access authority
8. Associate mother's demographics with newborn
9. Track incomplete preventative care opportunities
10. Flag special health care needs

ONC CERTIFICATION CRITERIA TO SUPPORT PEDIATRIC CARE AND PRACTICE SETTINGS

CURRENT 2015 EDITION CRITERIA:

- Transitions of Care
- Care Plan
- View, Download, Transmit
- Application Programming Interface (API)
- Data Segmentation for Privacy
- Problem List
- Electronic Prescribing
- Common Clinical Data Set (CCDS)
- Social, Psychological, and Behavioral Data
- Clinical Quality Measure (CQM)
- Clinical Decision Support
- Immunizations
- Demographic data capture
- Family health history
- Patient health data capture
- Privacy and security

PROPOSED NEW 2015 EDITION CRITERIA:

- United States Core Data Set for Interoperability (USCDI)
- Electronic prescribing
- FHIR-based API
- Data segmentation for privacy

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Additional Requests for Information

Additional Requests for Information

- ONC Development of Similar Independent Program Processes to that of the FDA Software Pre-Certification Program

  » We request comment on whether ONC should establish new regulatory processes tailored towards recognizing the unique characteristics of health IT (e.g., EHR software) by looking first at the health IT developer, rather than primarily at the health IT presented for certification, as is currently done under the ONC Health IT Certification Program.

- Health IT and Opioid Use Disorder Prevention and Treatment

  » We request public comment on how our existing ONC Health IT Certification Program requirements and the proposals in the proposed rule may support use cases related to opioid use disorder (OUD) prevention and treatment and if there are additional areas that ONC should consider for effective implementation of health IT to help address OUD prevention and treatment.

- Assurances and the Trusted Exchange Framework and the Common Agreement (TEFCA)

  » We seek comment on whether certain health IT developers should be required to participate in the TEFCA as a means of providing assurances to their customers and ONC that they are not taking actions that constitute information blocking or any other action that may inhibit the appropriate exchange, access, and use of EHI.

- Exchange with Registries

  » We request comment on how a standards-based API might support improved information exchange between a health care provider and a registry to support public health reporting, quality reporting, and care quality improvement. Public input on this RFI may be considered for future HHS rulemaking to support the bidirectional exchange of clinical data between health care providers and registries for a wide range of use cases.

- Patient Matching

  » We seek comment on additional opportunities that may exist in the patient matching space and ways that ONC can lead and contribute to coordination efforts with respect to patient matching. ONC and CMS collaborated to jointly issue complementary requests for information regarding patient matching.

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21st Century Cures Act NPRM – Regulatory Implementation Milestones
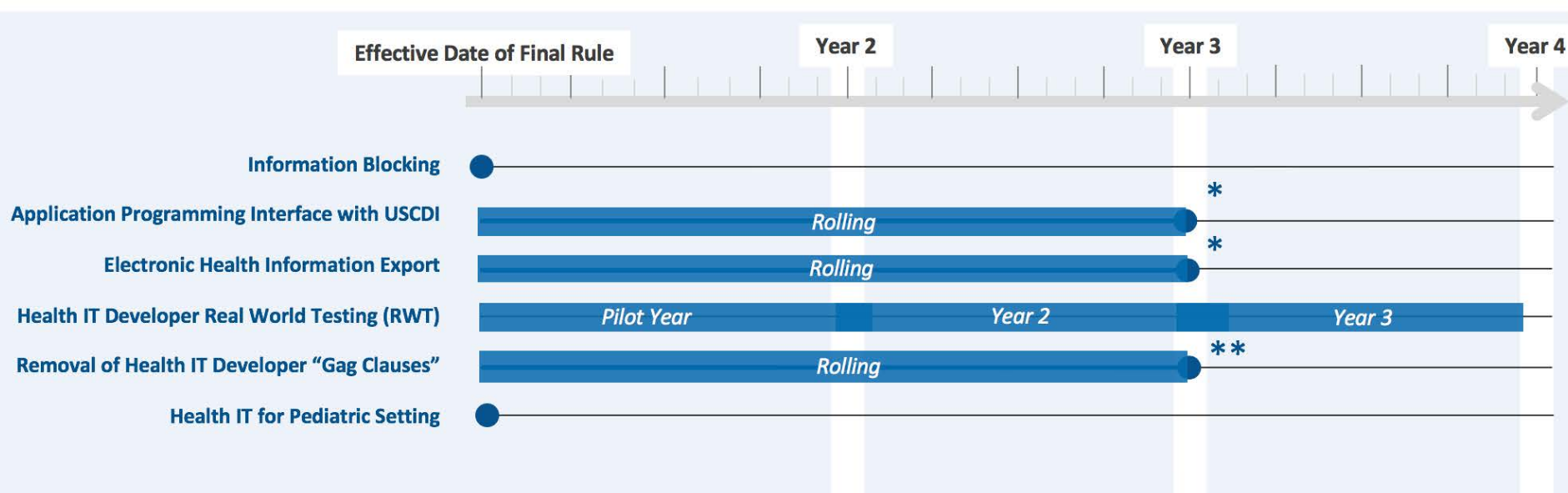
*Last day for health IT developers to implement for customers (health care providers)
**Last day to remove "gag clauses" from health IT contracts

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